Appl. No. 09/980,586 Amdt. dated August 23, 2004 Reply to Office Action of February 23, 2004

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1-97: (Canceled)

98. (Currently amended) A method for prophylactically or therapeutically treating Alzheimer's disease in a mammal human having Alzheimer's disease comprising administering to the mammal human a sufficient amount of a sterile aqueous suspension comprising at least 0.05 mg/ml of Aβ peptide in a regime effective to induce an immune immunogenic response comprising antibodies to the Aβ peptide the production of antibodies, wherein the sterile aqueous suspension is prepared by a process comprising:

(a) providing an aqueous composition comprising $A\beta$ peptide, wherein the pH of the composition is adjusted such that it is $A\beta$ is maintained at a physiologically acceptable pH and the suspension is prepared by adjusting the pH of an aqueous solution sufficient to solubilize said $A\beta$ peptide;

- (b) filtering the <u>aqueous composition</u> resulting suspension through a hydrophilic filter; and
- (c) adjusting to a physiologically acceptable the pH of the aqueous composition to a physiologically acceptable pH to form a sterile aqueous suspension comprising at least 0.05 mg/ml of Aβ peptideto form the aqueous suspension, and thereby prophylactically or therapeutically treat Alzheimer's disease in the mammal.
- 99. (Currently amended) The method of claim 98, wherein the resulting sterile aqueous suspension is maintained at a physiologically acceptable pH by use of about an effective amount of a pharmaceutically acceptable buffer.
- 100. (Previously presented) The method of claim 98, wherein the $A\beta$ peptide is a long form of $A\beta$ peptide.

- 101. (Previously presented) The method of claim 100, wherein said $A\beta$ peptide is $A\beta42$.
- 102. (Previously presented) The method of claim 98, wherein the physiologically acceptable pH is maintained at a pH of about 5 to about 7.
- 103. (Previously presented) The method of claim 102, wherein the physiologically acceptable pH is maintained at a pH is about 5.5 to about 6.5.
- 104. (Previously presented) The method of claim 99, wherein the pharmaceutically acceptable buffer is selected from the group consisting of amino acids, salts and derivatives thereof; pharmaceutically acceptable alkalizers, alkali metal hydroxides and ammonium hydroxides, organic and inorganic acids and salts thereof; and mixtures thereof.
- 105. (Previously presented) The method of claim 104, wherein the pharmaceutically acceptable buffer is an amino acid, salt and derivative thereof.
- 106. (Previously presented) The method of claim 105, wherein the pharmaceutically acceptable buffer is an amino acids, salts and derivatives thereof glycine (sodium glycinate) or arginine (arginine hydrochloride).
- 107. (Previously presented) The method of claim 104, wherein the pharmaceutically acceptable buffer is acetate (sodium acetate), or citrate (sodium citrate).
- 108. (Currently amended) The method of claim 98, wherein the sterile aqueous suspension has an A β 42 concentration of 0.1 to 0.8 mg/ml in a pharmaceutically <u>acceptable</u> effective buffer of 10 mM glycine, and the physiologically acceptable pH is maintained at a pH of about 5.5 to about 6.5.
- 109. (Previously presented) The method of claim 98, wherein the sterile aqueous suspension further comprises sucrose.

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- 110. (Currently amended) The method of claim 109, wherein the sucrose concentration of the sterile aqueous suspension is in amount of sucrose is sufficient to provide a 5% (w/v) sucrose suspension.
- 111. (Previously presented) The method of claim 98, wherein the sterile aqueous suspension further comprises polysorbate 80.
- 112. (Previously presented) The method of claim 98, wherein the sterile aqueous suspension is free of polysorbate 80.
- 113. (Previously presented) The method of claim 98, wherein the sterile aqueous suspension further comprises a pharmaceutically acceptable adjuvant.
- 114. (Previously presented) The method of claim 113, wherein the adjuvant is selected from the group consisting of incomplete Freund's adjuvant; MPL; QS-21 and alum.
- 115. (Previously presented) The method of claim 114, wherein the adjuvant is OS-21.
- 116. (Currently amended) The method of claim 115, wherein the sterile aqueous suspension is a visually clear suspension having an Aβ42 concentration of at least 0.1 mg/ml, an effective amount of QS-21 effective to form the visually clear suspension, and wherein the physiologically acceptable pH is maintained at a pH of about 5 to about 7.
- 117. (Currently amended) The method of claim 115, wherein the sterile aqueous suspension is a visually clear suspension having an Aβ42 concentration of 0.1 to 1.0 mg/ml in a pharmaceutically acceptable effective buffer of 10mM glycine, the adjuvant is at least 0.1 mg/ml of QS21, wherein and the physiologically acceptable pH is maintained at a pH of about 6.
- 118. (Currently amended) The method of claim 101, wherein the sterile aqueous suspension is a visually clear suspension further comprising an effective amount of

DPPC (dipalmitoyl phosphatidyl chloride) <u>effective to form the visually clear suspension</u>, <u>wherein and the physiologically acceptable pH is maintained at a pH of about 5 to about 7.</u>

- 119. (Previously presented) The method of claim 118, wherein the sterile aqueous suspension has an A β 42 concentration of at least 0.1 mg/ml and the physiologically acceptable pH is maintained at a pH of about 6.
- 120. (Currently amended) The method of claim 98, wherein the method further comprises administering a pharmaceutically acceptable adjuvant separately or admixed in within the said sterile aqueous suspension composition.
- 121. (Currently amended) The method of claim 113, wherein the sterile aqueous suspension is administered parentally parenterally.
- 122. (Currently amended) The method of claim 98, wherein the sterile aqueous suspension is administered parentallyparenterally.
- 123. (New) A method for prophylactically treating Alzheimer's disease in a human at risk of developing Alzheimer's disease comprising administering to the human a sufficient amount of a sterile aqueous suspension comprising $A\beta$ peptide in a regime effective to induce an immune response comprising the production of antibodies, wherein the sterile aqueous suspension is prepared by a process comprising:
- (a) providing an aqueous composition comprising $A\beta$ peptide, wherein the pH of the composition is adjusted such that it is sufficient to solubilize said $A\beta$ peptide;
 - (b) filtering the aqueous composition through a hydrophilic filter; and
- (c) adjusting the pH of the aqueous composition to a physiologically acceptable pH to form a sterile aqueous suspension comprising at least 0.05 mg/ml of Aβ peptide.
- 124. (New) The method of claim 123, wherein the sterile aqueous suspension is maintained at a physiologically acceptable pH by use of a pharmaceutically acceptable buffer.

- 125. (New) The method of claim 123, wherein the $A\beta$ peptide is a long form of $A\beta$ peptide.
 - 126. (New) The method of claim 125, wherein said A β peptide is A β 42.
- 127. (New) The method of claim 123, wherein the physiologically acceptable pH is maintained at a pH of about 5 to about 7.
- 128. (New) The method of claim 127, wherein the physiologically acceptable pH is maintained at a pH is about 5.5 to about 6.5.
- 129. (New) The method of claim 124, wherein the pharmaceutically acceptable buffer is selected from the group consisting of amino acids, salts and derivatives thereof; pharmaceutically acceptable alkalizers, alkali metal hydroxides and ammonium hydroxides, organic and inorganic acids and salts thereof; and mixtures thereof.
- 130. (New) The method of claim 129, wherein the pharmaceutically acceptable buffer is an amino acid, salt and derivative thereof.
- 131. (New) The method of claim 130, wherein the pharmaceutically acceptable buffer is an amino acids, salts and derivatives thereof glycine (sodium glycinate) or arginine (arginine hydrochloride).
- 132. (New) The method of claim 131, wherein the pharmaceutically acceptable buffer is acetate (sodium acetate), or citrate (sodium citrate).
- 133. (New) The method of claim 123, wherein the sterile aqueous suspension has an A β 42 concentration of 0.1 to 0.8 mg/ml in a pharmaceutically acceptable buffer of 10 mM glycine, and the physiologically acceptable pH is maintained at a pH of about 5.5 to about 6.5.
- 134. (New) The method of claim 123, wherein the sterile aqueous suspension further comprises sucrose.

- 135. (New) The method of claim 135, wherein the sucrose concentration of the sterile aqueous suspension is 5% (w/v).
- 136. (New) The method of claim 123, wherein the sterile aqueous suspension further comprises polysorbate 80.
- 137. (New) The method of claim 123, wherein the sterile aqueous suspension is free of polysorbate 80.
- 138. (New) The method of claim 123, wherein the sterile aqueous suspension further comprises a pharmaceutically acceptable adjuvant.
- 139. (New) The method of claim 138, wherein the adjuvant is selected from the group consisting of incomplete Freund's adjuvant; MPL; QS-21 and alum.
 - 140. (New) The method of claim 139, wherein the adjuvant is QS-21.
- 141. (New) The method of claim 140, wherein the sterile aqueous suspension is a visually clear suspension having an Aβ42 concentration of at least 0.1 mg/ml, an amount of QS-21 effective to form the visually clear suspension, wherein the physiologically acceptable pH is maintained at a pH of about 5 to about 7.
- 142. (New) The method of claim 140, wherein the sterile aqueous suspension is a visually clear suspension having an Aβ42 concentration of 0.1 to 1.0 mg/ml in a pharmaceutically acceptable buffer of 10mM glycine, at least 0.1 mg/ml of QS21, wherein the physiologically acceptable pH is maintained at a pH of about 6.
- 143. (New) The method of claim 126, wherein the sterile aqueous suspension is a visually clear suspension further comprising an amount of DPPC (dipalmitoyl phosphatidyl chloride) effective to form the visually clear suspension, wherein the physiologically acceptable pH is maintained at a pH of about 5 to about 7.

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- 144. (New) The method of claim 143, wherein the sterile aqueous suspension has an A β 42 concentration of at least 0.1 mg/ml and the physiologically acceptable pH is maintained at a pH of about 6.
- 145. (New) The method of claim 123, wherein the method further comprises administering a pharmaceutically acceptable adjuvant separately or admixed in within the said sterile aqueous suspension.
- 146. (New) The method of claim 138, wherein the sterile aqueous suspension is administered parenterally.
- 147. (New) The method of claim 123, wherein the sterile aqueous suspension is administered parenterally.